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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,026

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Basant Kumar Puri

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,026	<b>Applicant(s)</b> PURI, BASANT KUMAR	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-67 is/are pending in the application.
- 4a) Of the above claim(s) 53, 66 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-52 and 54-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 Sept 2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Response to Election of Species and Restriction Requirement***

Applicant's election with traverse of eicosapentaenoic acid in the reply filed on February 8, 2008 is acknowledged. The traversal is on the ground(s) that eicosapentaenoic acid is not a class of compounds but a distinct compound in and of itself. This is not found persuasive because the claims not only recite eicosapentaenoic acid but also esters of eicosapentaenoic acid thereby encompassing not only more than one compound but several compounds.

Applicant's election without traverse of primrose oil and Invention I in the reply filed on February 8, 2008 is acknowledged.

Claims 53, 66 and 67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 8, 2008.

The requirement is still deemed proper and is therefore made FINAL.

## ***Claims***

### **Claim Objections**

Claim 65 is objected to because of the following informalities: a "," should be incorporated in between the terms "tablet" and "capsule" in the second line of the claim. Appropriate correction is required.

**Claim Rejections - 35 USC § 112 – Written Description**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-52 and 57-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’)

Mere indistinct terms (such as “triterpene or an ester thereof” used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening

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inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, the courts have indicated what does not constitute same. See, e.g., In re Gostelli, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two chemical compounds within a subgenus did not adequately describe such subgenus.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that

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distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful triterpene or esters thereof generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. The specification appears to only provide support for fused ring triterpenes such as 3-O-trans caffeoyl derivative of betulinic acid, morolic acid or oleanolic acid, faradiol-O-laurate, faradiol-O-palmitate or faradiol-O-myristate. Naturally occurring triterpenes can be isolated from a variety of plants including the flower heads of marigolds (*Calendula officinalis*), *Zygophyllum eichwaldii*, *Carthamus lanatus*, *Oenothera bienni* (evening primrose) or *Pyrus comminus*. The specification does not provide any other types of triterpene or esters thereof or how to identify other triterpenes or ester thereof that are suitable for use in the instant invention. Even with the disclosure of the term “triterpenoids”, these terms still encompass numerous compounds, especially considering that the terms encompass both natural and synthetic triterpenes, which vary structurally and vary in activities. There is no disclosure of the specific structure, characteristics or functions of the triterpenes that make it suitable for the suitable for the instant invention other than those disclosed above. Even in the case of the naturally occurring triterpenes, indication of from where the component is isolated gives not indication of its structure as to direct one to reasonable look to other sources to isolate similar materials.

**Claim Rejections - 35 USC § 112 - Indefiniteness**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 49-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 47 and 65 comprise the term “substantially”. The specification does not seem to adequately define the relative term “substantially”, such that the metes and bounds of same are not clear.

2) 1) Claim 51 comprises the term “pure”. The specification does not seem to adequately define the relative term “pure”, such that the metes and bounds of same are not clear.

**Claim Rejections - 35 USC § 102 - Anticipation**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 47-52, 54-63 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 5,145,686).

Horrobin et al. disclose topical pharmaceutical compositions. The compositions comprise evening primrose oil and eicosapentaenoic acid (see Examples 12 and 13). Primrose oil comprises up to 8 percent by weight of the composition (see Examples). Primrose oil or *Oenothera biennis* L comprises gamma linoleic acid (col. 4, lines 52-57). Primrose oil comprises gamma linoleic acid thereby encompassing claims 62 and 63. In regards to claim 56, the reference does not disclose the primrose oil as being refined and therefor it can be concluded that the oil is a virgin oil, Encompassing claim 56. Eicosapentaenoic acid comprises 0.1 to 20 percent by weight of the compositions. It can be concluded the Eicosapentaenoic acid is pure because the reference does not indicate that it is available as a component of another source, encompassing claim 51. In regards to claims 50, eicosapentaenoic acid is isolated from fish oil, Encompassing claim 50. The compositions are formulated into ointments and comprise an appropriate ointment base. The compositions do not comprise docosahexaenoic acid. The reference anticipates the instant claims insofar as it discloses compositions for the skin comprising eicosapentaenoic acid; a triterpene primrose oil and a compound for co-administration, conjugated linoleic acid and gamma linolenic acid.

2) Claims 47-52 and 57-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Bettel et al. (US 2003/0104018).



Bettle et al. disclose compositions for the skin comprising two phases. The compositions comprise Shark liver oil, Eicosapentaenoic acid, conjugated linoleic acid and gamma linolenic acid (Exampe 7). Shark liver oil comprises squalene, which is a triterpene<sup>1</sup>. The composition is and emulsion and comprises a carrier as recited in claim 61. The composition does not comprise docosahexaenoic acid. The reference anticipates the instant claims insofar as it discloses compositions for the skin comprising eicosapentaenoic acid, a triterpene and a compound for co-administration, conjugated linoleic acid and gamma linolenic acid.

Claims 47-52 and 54-65 are rejected.

Claims 53, 66 and 67 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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<sup>1</sup> Scaffidi US 4,816,271, col. 1, lines 30-40.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612